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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,533	07/29/2003	Ronald J. Thompson	Thompson-10A	6052
7590 Donald N. Halgren 35 Central St. Manchester, MA 01944		06/11/2007	EXAMINER LANDSMAN, ROBERT S	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 06/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/629,533	Applicant(s) THOMPSON, RONALD J.	
	Examiner Robert Landsman, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Formal Matters

A. Claims 1-4 are pending and are the subject of this Office Action.

2. Specification

A. The Figures are objected to. It is noted that some Figures are labeled with Roman numerals, others use Arabic. The Roman numerals do not correspond to those in the Brief Description of the Drawings, which uses Arabic numerals.

Furthermore, there is hand-written information on the Figures. When submitted, the Formal Drawings should be clean and legible.

3. Claim Objections

A. Claims 3 and 4 are objected to since it is not clear how one can “suppress” a volume. It is suggested that the term “of reducing” be used, for example, or a similar term which does not add new matter.

3. Claim Rejections - 35 USC § 112, first paragraph – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

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First, the breadth of the claims is excessive with regard to claiming methods of suppressing appetite in a mammal by stimulating ghrelin release, depleting ghrelin and blocking ghrelin in the brain. Applicants have not provided any guidance or working examples of any method of performing the claimed invention, including the possible use of any ligands able to stimulate, deplete or block ghrelin. All that has been disclosed in the specification is that ghrelin is involved in appetite stimulation. It is not predictable to the artisan how to stimulate and deplete ghrelin, nor how to block ghrelin in the brain. No ligands which are able to cross the blood brain barrier have been disclosed, nor have any other.

Furthermore, though ghrelin has been shown to stimulate appetite, Applicants have not provided any evidence that inhibiting ghrelin would suppress appetite, nor have they provided any guidance or working examples of which "portion of any ghrelin activity" can be blocked to produce the desired effect. For these reasons, the Examiner concludes that undue experimentation is necessary to practice the invention as claimed.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The claims recite any and all methods of suppressing appetite in a mammal by stimulating ghrelin release, depleting ghrelin and blocking ghrelin in the brain by using any ghrelin compounds. Applicants have not provided any description of any such methods. Regarding the possible use of compounds used to modulate ghrelin, the specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the ligand class are missing from the disclosure.

No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the recited steps alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure

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fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of “a **portion** of any ghrelin **activity**” are not known. Applicants have not taught what specific activity of ghrelin is responsible for appetite suppression, nor have they disclosed what are the metes and bounds of “a portion.”

6. Prior Art/Art of Interest

A. As Applicants have disclosed, the prior art has clearly demonstrated that ghrelin is involved in appetite stimulation. However, the Examiner is unable to make a prima facie case that the present invention is obvious as the prior art, at the time of the invention, was unable to provide support for the presently claimed methods even though the concept of suppressing appetite by modulating ghrelin appeared obvious.

B. Nakazato et al. (Nature) teach a role of ghrelin in the central regulation of feeding as well as antagonists which abolish ghrelin-induced activity (Abstract). Again, however, a prima facie case could not be made that the method of Nakazato meet the presently claimed methods.

7. Conclusion

A. No claim is allowable.


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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres at 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert Landsman, Ph.D.
Primary Examiner
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